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1200 Pennsylvania Avenue, NW
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Attention: Docket ID Number EPA-HQ-OPPT-2016-0401

Submitted to the Federal eRulemaking Portal (www.regulations.gov)

Re: Environmental Protection Agency's Consultation on TSCA Fees

Dear Ms. Cunningham:

The American Fuel & Petrochemical Manufacturers (AFPM) respectfully submits the attached comments on the Environmental Protection Agency's (EPA or Agency) Consultation on TSCA Fees, in response to the Agency letter dated July 26, 2016.

AFPM is a national trade association representing nearly 400 companies that encompass virtually all U.S. refining and petrochemical manufacturing capacity. AFPM refining and petrochemical member companies are subject to the Toxic Substances Control Act (TSCA) and will be directly impacted as EPA implements the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

AFPM supports EPA's efforts to consult with parties affected by the collection of fees related to TSCA activities. Additionally, AFPM has long supported TSCA modernization and looks forward to working with EPA and other stakeholders throughout the implementation process.

Sincerely,

Melissa Hockstad
Vice President, Petrochemicals

AFPM Comments on TSCA Fees

August 24, 2016

Docket ID No. EPA-HQ-OPPT-2016-0401

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COMMENTS BY TOPIC

The following comments are organized by general topic.

1.0 TRANPARENCY

1.1 EPA must create a transparent process by which fees are collected.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act authorizes EPA to collect fees for services rendered under Sections 4 (“Industry Testing Requirements”), 5 (“Manufacturing and Processing Notices”), and 6 (“Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures”), including the maintenance of confidential business information (CBI). Fees should be well-understood by all affected parties, including the specific services and timelines for which the fees apply. Methodologies and assumptions used to assess fees should be clear and concise. Specifically, the fees should be transparent and proportional to the amount of effort put in by EPA to conduct the evaluations. The fees should avoid using irrelevant factors such as production volume or other misleading surrogates.

1.2 AFPM strongly supports the consultation process established by EPA.

Section 26(b)(4)(E) requires the Agency to consult with “parties potentially subject to the fees.” AFPM supports the process established by EPA and encourages further consultation, due to the complexities associated with risk evaluations under Section 6. Several scenarios have been put forth that readily demonstrate the challenges with establishing an equitable fee structure of chemicals with multiple uses. For example, there may be instances where a chemical has some uses that only require a cursory review, while other uses for that same chemical may require in-depth risk evaluation. Further dialogue is necessary to address these kinds of challenges.

1.3 EPA should estimate all direct and indirect costs associated with the implementation of Sections 4, 5 and 6, prior to establishing fees.

EPA will not be able to appropriately structure fees for services without an understanding of the costs borne by the Agency. EPA intends to include indirect costs in the fee structure, which further complicates the application of an equitable fee structure. AFPM urges EPA to quickly develop estimates on key components of services and the Agency’s expectations for recovering indirect costs.

An additional challenge to structuring fees is lack of clarity on the various risk evaluation processes that can be conducted. One element for consideration is that the fees should be tied directly to the scope of the evaluation, which could serve as a means for estimating the amount of work EPA expects for the evaluation. In fact, when retaining the services of a contractor, it is common to receive a description of the scope of work and a corresponding breakdown of fees associated with key steps in the process. EPA should look to the contracting practices of private consultants when assessing fees for its services.

2.0 PRESERVATION OF AMERICAN INNOVATION

2.1 Fees associated with Section 5 must not impede American innovation.

The United States is known globally for innovation, especially in the field of chemistry. A simple assessment of the number of new chemicals introduced in the U.S. on an annual basis, compared to other regions, shows that innovation is much stronger here than abroad. The main reason for such disparate numbers is the low financial barrier of entry into the U.S. marketplace. EPA employs a tiered and risk-

based approach to new chemical risk evaluations, versus a no-data-no-market approach, and has collected modest fees to help cover the cost of reviewing pre-manufacture notices (PMNs).

Fees for risk evaluations of Section 5 notices should be set at a level that corresponds to the amount of work expected by the Agency, but not to the point that the fees act as a deterrent to companies introducing new chemicals into the marketplace. Fees associated with the protection of CBI should also not impede innovation. Companies can gain an advantage by protecting certain intellectual property through CBI claims. CBI fees could penalize those who get a competitive advantage by having a unique molecule or unique use. Further dialogue will be necessary to address the challenge of finding balance between appropriate coverage of services and the preservation of American innovation.

3.0 TIMING OF FEE ASSESSMENTS

3.1 EPA should assess and collect fees at different points of the review process.

It is rare in the private sector that a customer is expected to pay all costs for services upfront. That should also be the case with fees associated with government services, especially if the fees apply to services that have specific deadlines. Collecting a fee upfront will help establish necessary funding for EPA to carry out its work. Collecting the full amount, however, would not provide any incentive for the Agency to complete its work on time. EPA should consider a series of payments at strategic points during the risk evaluation processes under Sections 5 and 6.

4.0 FEE AMOUNTS

4.1 EPA should not collect fees for information submitted under Section 4, then additionally collect fees for evaluation of that same information under Section 5 or 6.

AFPM anticipates that EPA will issue test rules, consent agreements and orders under Section 4 to require new testing on chemicals. Those Section 4 actions must have a purpose related to risk evaluation; therefore, the time to collect those fees should be consistent with collection of fees associated with risk evaluations. To charge two separate fees will be akin to double-charging for evaluation of the same information. For example, if EPA conducts a risk evaluation under Section 5 for a new chemical and requires a company to develop new test data, that data will be reviewed as part of the review of the PMN. Charging a fee for both the submittal of the test results and review under Section 5 is double-charging for the same data.

4.2 Fees for Significant New Use Notifications (SNUNs) should be lower than fees for PMNs.

PMNs cover the entire lifecycle of a chemical substance, while SNUNs only cover a particular use. The burden on EPA is much less for the review of a SNUN than for a PMN; therefore, a lower fee should apply.

4.3 Fees for exemptions under Section 5 should be lower than fees for PMNs.

Test Market, Low Volume-Low Exposure and other exemptions have specific requirements that apply to those seeking an alternative route into the marketplace. Those requirements are set forth upfront and designed to minimize risks; therefore, the review of those applications is a lesser burden on the Agency compared to the PMN review process. Consistent with AFPM's recommendations that fees correspond to the level of work EPA must devote to the task, AFPM recommends that fees for processing exemptions under Section 5 should be lower than fees for processing PMNs.

5.0 ROLES AND RESPONSIBILITIES

5.1 EPA should allow manufacturers and processors to confirm responsibilities among themselves and only play a limited role.

AFPM member companies have vast experience in both domestic and foreign voluntary and regulatory programs that involve the formation of consortia. The requirements under programs such as Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), with respect to consortia, are different than under TSCA. TSCA does not prescribe the responsibilities of consortium members; therefore, it is best to leave those functions up to the consortium members themselves.

If necessary, EPA could play a convening role during the formation of a consortium by helping to identify other market players and processors. The Agency could also have a potential role as an arbitrator if a dispute arises that cannot be resolved within the consortium.

5.2 The scope of industry-initiated risk evaluations should be determined by the company or consortium requesting the evaluation.

Section 6 allows manufacturers to request that EPA conduct a risk evaluation on a substance. Those manufacturers may wish to only cover certain uses. Since those manufacturers are required to cover the entire cost of the evaluation, it is appropriate to allow them to define the scope of that evaluation. If EPA determines that the scope should be broadened to include uses outside of those identified by the sponsor, the Agency can use its authorities and conduct evaluations for the other uses under Section 6(b).